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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,901	03/19/2001	Jeffrey A. Hubbell	262/304US	1025

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EXAMINER	
BERMAN, SUSAN W	

ART UNIT	PAPER NUMBER
1711	7

DATE MAILED: 10/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/811,901	Applicant(s) HUBBELL ET AL.	
	Examiner Susan W Berman	Art Unit 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 129-147* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 129-147* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 July 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Drawings

The corrected or substitute drawings were received on 07-24-2002. These drawings are acceptable with respect to Figures 1, 2a, 3, 5, 8, 9, 10 and 11a.

New corrected drawings are required in this application because Figures 2b, 4, 6 7a, 7b, 11b, 12a, 12b and 13 are unclear and unacceptable for printing. The original Figures 2b, 4, 6 7a, 7b, 11b, 12a, 12b and 13 are much clearer than the Figures filed 07-24-2002; however, they are not as clear as the drawings in Patent 5,529,914.

Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

The substitute specification submitted 07-24-2002 has not been entered because the claims are not the original claims filed in the application. It is noted that applicant cancelled claims 2-128 in a preliminary amendment, however, these are the claims originally filed in the specification.

Response to Amendment

Newly submitted claims 2-20 have been renumbered claims 129-147, according to Rule 1.126.

The rejection of claims 1 under 35 U.S.C. 102(b) as being anticipated by Fukui et al (4,195,129) is withdrawn. The rejection of claim 1 under 35 U.S.C. 103(a) as being unpatentable over Kaetsu et al (4,321,117) in view of Fukui et al is withdrawn. Fukui et al teach encapsulating enzymes or microbial cells and do not teach encapsulating an islet cell. Kaetsu et al disclose a method of encapsulating a physiologically active substance, not including animal cells.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 139-147 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising microencapsulating a biological material and then coating the microencapsulated material with a photoinitiator, does not reasonably provide enablement for a method of coating an islet cell with photoinitiator. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. See page 16.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 129-147 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims do not clearly recite that the islet cell is encapsulated in a microcapsule before creating a mix of islet cell, aqueous macromer solution and photoinitiator (claim 1) or before coating the islet with a photoinitiator (claim 139). It is suggested that the claims contain the phrase "at least one islet cell encapsulated in a microcapsule" or include a method step for encapsulating the islet cell in a microcapsule.

Claim Rejections - 35 USC § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 129-138 are rejected under 35 U.S.C. 102(e) as being anticipated by Soon-Shiong et al (5,700,848 or 5,705,270 or 5,846,530). See the Abstract and Examples 16-18 in US '848. Soon-Shiong teaches that the disclosed macrocapsules may contain cells that are encapsulated within microcapsules (column 9, lines 22-24, Example 26). With respect to claim 130, Soon-Shiong teaches poly(ethylene glycol), poly(amino acids), polysaccharides and proteins. Coextrusion is taught in Examples 16, 20 and 26. An accelerator to increase the rate of polymerization is taught in column 7, lines 37-49. With respect to claim 131, Soon-Shiong et al do not teach PEG tetraacrylate. However, the claim, as written, does not limit the macromer to being PEG tetraacrylate, it merely states that the PEG in the Markush group is PEG tetraacrylate.

Claims 1, 129-135 and 137-138 are rejected under 35 U.S.C. 102(e) as being anticipated by Soon-Shiong et al (5,545,423 or 5,759,578 or 5,788,988 or 5,879709). See the Abstract, column 7, line 43, to column 8, line 14, column 8, line 37, to column 9, line 14, column 11, line 64, to column 12, line 32, and Examples 5, 6 and 7 in US '423. Soon-Shiong teaches a method of microencapsulating cells such as islets and then encapsulating the microspheres in macrocapsules. With respect to claim 130, Soon-Shiong teaches polymerizable alginate, water-soluble poly(alkylene glycol), poly(amino acids), polysaccharides and proteins. An accelerator to increase the rate of polymerization is taught in column 10, lines 36-48. With respect to claim 131, Soon-Shiong et al do not teach PEG tetraacrylate. However, the claim, as written, does not limit the macromer to being PEG tetraacrylate, it merely states that the PEG in the Markush group is PEG tetraacrylate. With respect to claim 132 or 133, the claims, as written, do not limit the method of claim 3 to selection of polysaccharides or proteins from the Markush group set forth.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 129-147 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-69 of U.S. Patent No. 5,529,914. Although the conflicting claims are not identical, they are not patentably distinct from each other because the biological cells recited in the claims of US '914 include islet cells (see claim 20) and cells first encapsulated in microcapsules (see claim 2).

Claims 1 and 129-147 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 6258870. Although the conflicting claims are not identical, they are not patentably distinct from each other because the biological cells recited in the claims of US '914 include islet cells (see claim 15) and cells first encapsulated in microcapsules (see claim 50).

Claims 1 and 129-147 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5858746. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of

US '746 recite the same steps for encapsulating mammalian cells using initiation by light. See claims 1, 16, 18 and 31.

Claims 1 and 129-147 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5801033. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US '033 recite the same steps for encapsulating mammalian cells as set forth in the instant claims. See claims 1, 2, 11 and 12.

Claims 139-147 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5843743. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed method steps are recited in the method for forming a coating on a substrate wherein the substrate can be a microencapsulated cell. See claims 1, 8 and 16. It would have been obvious to one skilled in the art at the time of the invention to select an islet cell as the biologically active material for the substrate in the claims of US '743 because islets are specifically taught. See the Abstract.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W Berman whose telephone number is 703 308 0040. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30. The examiner can also be reached on alternate .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck, can be reached on (703) 308 2462.

The fax phone number for the organization where this application or proceeding is assigned is 703 872 9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0661.

Susan Berman

Susan W Berman
Primary Examiner
Art Unit 1711

S B
October 07, 2002